

REMARKS

The Office Action mailed December 7, 2007, has been received and reviewed. By the present Response, Claims 26 and 28-30 are canceled, Claims 14-15, 21, 24-25, 31, and 38 are amended, and new Claims 40-43 are added. Currently pending in the application, then, are Claims 1, 3-25, and 31-43, of which Claims 1, 14, 21, 24, 25, 31, and 33 are independent. No new matter has been introduced by this Response. The Applicant respectfully traverses the rejections and requests reconsideration.

Claim Rejections Under 35 USC § 102

Claims 14 and 15 stand are rejected under 35 U.S.C. 102(a) as being allegedly anticipated by Ours (US 4,048,471). The applicant respectfully traverses this ground of rejection.

The Ours reference discloses a heated spreader blade assembly having a blade for spreading, smoothing, and curing plastic filler material, as is used in filling automobile body dents. Thus, "blade" in the context of this reference means a thin, wide, flat-sided, panel-like part for pushing and smoothly spreading material (e.g., as in an oar blade or a spatula blade). On the other hand, "blade" in the context of microkeratomes for laser refractive eye surgery means a flat, extremely sharp-edged, precision-made part for cutting. (Plus, the claimed invention is not even a "blade" by either meaning, as it has a blunt separating edge that separates by peeling back instead of cutting.) So these spreader and microkeratome blades are different types of blade structures designed for entirely different functions. This distinction is recited in the claim language calling for a "separating edge" for separating the epithelium from the Bowman's layer of a cornea, while the blade of the Ours reference is a panel-like blade with large sides for spreading dent-filler and with a straight lower edge for smoothing the dent-filler but not for cutting or otherwise separating anything.

In addition, the Ours reference is in the field of assemblies for spreading material to fill dents in automobile bodies, which is quite remote from and completely unrelated to microkeratomes for laser refractive eye surgery. In fact, the cited reference is included in 2 International Classifications and 8 U.S. Classifications, and the field of search during its prosecution included 34 International Classifications (as indicated on the cover sheet of the patent). But the International and U.S. Classifications of the present application are not included in any those classes. Because dent-filler spreaders are so far afield from microkeratomes for laser refractive eye surgery, a person of ordinary skill in the art designing advanced microkeratomes would not look to the field of heated dent-filler spreaders for guidance.

To more clearly recite this distinction, independent Claim 14 is amended to recite that the separator is used with a surgical device including a positioning ring for attachment to the eye and a guide for controlling the travel of the separator across the eye to separate epithelium from the underlying Bowman's layer. This even further distinguishes the field of the claimed invention from dent-filler spreaders.

For all of these reasons, the Applicant submits that the Ours reference does not disclose the claimed invention and is not pertinent art to the claimed invention. Accordingly, the Applicant requests reconsideration and withdrawal of this rejection of Claims 14 and 15.

The Applicant notes that this reference appears to be cited in this Section 102 rejection at least in part for disclosing the use of reinforcing glass fibres in plastic blade assemblies and/or the use of nylon in blade assemblies. The claims that recite glass fibers are Claims 9 and 21, and the claims that recite nylon are Claims 3 and 15. As discussed above, the Applicant believes that the Ours reference is not pertinent and that therefore this rejection should be withdrawn, so Claims 3 and 9 have not been amended.

Nevertheless, to expedite prosecution, the Applicant has amended Claim 21 to delete the recital of “glass fibers” and amended Claim 15 to delete the recital of “nylon.”

Claim Rejections Under 35 USC § 103

Claims 16-20 and 25 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ours. As discussed above, the Ours reference is not believed to disclose or be pertinent art to the claimed invention because these are different types of blades used in entirely different fields. This is particularly true in light of the amendments to Claims 14 (from which Claims 16-20 depend) and 25 that add to the preambles that the separator is used with a surgical device including a positioning ring and a guide to separate epithelium from the underlying Bowman’s layer. Accordingly, the Applicant requests reconsideration and withdrawal of this rejection of Claims 16-20 and 25.

Claims 1-8, 13-20, 25-26, and 28-39 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Pallikaris et al. (US 7,004,953) in view of Foggia et al. (US 5,782,852). Claims 26 and 28-30 are canceled. The applicant respectfully traverses the remaining grounds of rejection.

Independent Claims 1, 14, 21, 25, 31, and 33 all recite structures including, or methods of using, a separator that is used with a surgical device including a positioning ring and a guide, with the separator including a polymeric separating edge to separate epithelium from the underlying Bowman’s layer. (Claim 21 does not appear to be specifically dealt with in the Office Action, but has been addressed in the Response due to its recital of a polymeric separating edge.)

First of all, the Applicant admits that in many situations a selection of a known material by itself is oftentimes within the ordinary skill of those who practice in the particular art and thus material selection oftentimes does not rise to the level of being non-obvious and patentable. However, in some arts where there has been a long history of development in the use of a certain type of material for a highly specialized structure, then

the use of an existing material that had never before been used in that application could in fact be a radical departure from the prior art that could raise to the level of patentability. The Applicant submits that this is such a case.

The claims recite a separator having a separating edge that is made at least in part of a *polymeric* material. The polymeric separating edge is not sharp enough to cut into the underlying Bowman's layer—it is “blunt”—so it separates the corneal epithelium from the Bowman's layer while *leaving the Bowman's layer intact*. As discussed in the specification (see para. [0004] to [0006]), all known prior microkeratomes include a sharp-edged knife or blade made of metal, diamond, or a similar hard material. In addition, all known prior microkeratomes, except for that disclosed by Pallikaris (which the Applicant has an ownership interest in), include such a knife or blade for cutting *all the way through the epithelium and the Bowman's layer, and into the stroma*. And while the Pallikaris reference discloses a microkeratome for separating the epithelium from the cornea, even it uses a sharp-edged metal knife for doing so.

Thus, until the present invention, all of the known research and development in the area of blades for microkeratomes for laser refractive eye surgery—over a period of about 40 years beginning in about 1962—was focused on finding ways to make the blades of a harder material that can hold a sharper edge. Conventional polymeric materials are not capable of holding a sharp enough of an edge to perform the precise corneal cutting required in eye surgery. So the prior art, which is voluminous, teaches away from the use of a separator having a *polymeric* separating edge for separating the epithelium from the cornea and leaving the Bowman's layer intact, as is claimed. But this has proven to be a significant advance in the field of corrective eye surgery because, among other reasons, the polymeric separators can be made inexpensively enough that they can be used only once and then disposed of. This disposability feature avoids the problems associated with sterilization and contamination from re-use. In addition, by using the blunt separating edge to scrap back only the epithelial layer and thereby expose an intact Bowman's layer, an

optical correction can be made to the Bowman's layer without cutting into and permanently damaging nerves in the Bowman's layer and stroma. Because the epithelial layer is regenerative and only this thin layer is removed, the eye heals much more quickly and completely.

In addition, the claimed invention was invented contemporaneously with, and quite possibly before, the Pallikaris device was, at a time when all microkeratomes included, and always had included, a sharp blade made of metal or another hard material selected for holding a sharp edge. The Pallikaris reference discloses using a blunt blade to separate epithelium from the underlying Bowman's layer, but even this device uses a metal blade, as this has been the long-standing convention for about 40 years. The Pallikaris reference was not published until after the provisional filing date of the present application, so even though this reference may be prior art against the present application, it was not publicly known at the time of the provisional filing of the present application. So at the time the present invention was made, its inventors could not possibly have known of the Pallikaris device, and the use of a polymeric separator in a microkeratome was truly a radically innovative concept.

Furthermore, the Foggia reference does not disclose, suggest, or teach using a polymeric material in a separating edge of separator of a microkeratome for use in laser refractive eye surgery. This reference discloses a finger-sticking device for creating a puncture wound from which a blood sample can be obtained. In particular, the finger-sticking device includes a "blade" with a "sharp apex" that "incises" the skin. The Examiner asserts that this reference and the claimed invention are both in the surgical arts. However, the surgical arts is a vast multidisciplinary field with many quite highly specialized areas. A designer pursuing safer and more precise designs in blades for microkeratomes for use in refractive eye surgery would not reasonably be expected to investigate finger-sticking devices. This is particularly true in light of the above discussion about how all of

the efforts in developing improved microkeratome blades have been focused on making blades that are harder and hold a sharper edge.

For these reasons, the cited references do not disclose, teach, or suggest the claimed blunt polymeric separating edge for separating the epithelium from the Bowman's layer while leaving the Bowman's layer intact. Accordingly, Claims 1, 14, 21, 25, 31, and 33 are believed to be in condition for allowance. Claims 1-8, 13-20, 25, and 31-39 all depend from these independent claims, so these claims are also believed to be in condition for allowance.

In addition, Claim 38 recites the step of not constraining the epithelium during the separation. As described in the specification as para. [0053] and [0054], this results in less stress and strain on the epithelium and thus less cell death. And Claim 39 recites the step of disposing of the separator (with the *polymeric* separating edge) after a single use. Neither of these recited elements are disclosed, taught, or suggested by the cited references. These claims do not appear to have been specifically addressed in the Office Action.

New Claims

New Claims 40-43 recite additional subject matter related to the shape of the separating edge. This newly recited matter is supported by the application as filed in FIGS. 3-5 and para. [0033], so no new matter is added. In contrast, the separator of Pallikaris has a leading edge that is rounded but symmetrical (col. 6, lines 19-21; FIG. 22) or that is flat but symmetrical and in the range of 5-25 microns thick (col. 6, lines 16-18; FIG. 21).

Allowable Claims

Claims 9, 11, 12, 23, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims. These claims will be rewritten in independent form in response to a subsequent Office Action.

CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, the Applicant respectfully requests early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone the Applicant's undersigned attorney at (770) 984-2300.

Respectfully submitted,

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